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10/003,850	11/02/2001	Sreekumar Pillai	J6673(C)	6359

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EXAMINER

KANTAMNENI, SHOBHA

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/003,850	Applicant(s) PILLAI ET AL.	
	Examiner Shobha Kantamneni	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/2007 has been entered.

Applicant's amendment filed on 10/30/2007, wherein independent claims 1, and 5 have been amended. Applicant's amendment also added new claims 11-12.

Newly submitted claims 11-12 are directed to an invention that is independent or distinct from the invention originally elected. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 2, 5-6, and 9-10 are pending, and examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (US 5,723,139, PTO-892 of record) and Gorbach (WO 98/56373, PTO-892), in view of Liu et al. (5,976,555, PTO-892 of record), and Surares et al. (US 5,914,116, PTO-1449 of record).

Granger et al. teach a skin conditioning composition comprising a compound selected from retinal or retinyl ester in an amount from about 0.001 % to about 10 %, in combination with a retinoid booster, polycyclic triterpene carboxylic acid, glycyrrretinic acid in an amount from about 0.0001 % to about 50%. See column 1, line 42-column 3, line 39. It is further taught that the combination of retinal or a retinyl ester with a polycyclic triterpene carboxylic acid, glycyrrretinic results in synergistic inhibition of keratinocyte differentiation. Retinoid boosters such as linoleic acid, arachidonic acid etc. are also disclosed as optional ingredients in the composition. See column 4, lines 29-38. The composition is applied to the skin for treating a skin conditions such as dry skin, photodamaged skin, appearance of wrinkles, age spots, acne, skin lightening etc. See column 12, claims 1-6. Granger et al. further disclose that the skin care composition therein is stored in a suitable container to form a skin care product. See column 11, EXAMPLE 6-7.

Granger et al. do not specifically teach the presence of phytoestrogens in the composition.

Granger et al. do not teach the storage of first composition comprising retinoid, and second composition comprising, glycyrrhetic acid, and phytoestrogens, in separate compartments joined together.

Gorbach teaches that phytoestrogens such as genistein, daidzein, glycitin, equol, formononetin are useful for treating wrinkles, aging skin etc. Phytoestrogens are present in an amount of 1 and 40 mg per gram of base. See abstract; page 2, lines 7-15; column 6, claims 1-4.

Liu et al. teach that retinoids such as retinal, retinyl ester in skin care compositions are unstable due to oxidation or isomerization to non-efficacious chemical forms with the result that the amount of retinoid actually present to provide the beneficial effects is reduced in a short period of time. See column 2, lines 40-55. It is further taught that several stable compositions for skin care are supplied in two bottles (separating retinoids from other cosmetic ingredients), portions of which are mixed together just prior to use. See column 2, lines 54-62.

Suares et al. teaches a method for a skin treatment regime and product that includes a first composition containing at least one active and functioning to impart a benefit to skin, and a second composition that includes a second different active and imparts a benefit to skin (see abstract, in particular). Suares et al. teaches that the first and second compositions are stored in respective separate containers, which are joined together (see abstract and column 2, lines 1-14, in particular.) Suares et al. teaches that the two compositions are kept separate because single formulations often compromise the performance of the severally combined actives (see column 1, lines 15-25, in

particular.) Accordingly, Soares et al. teachings provide a first composition in a first compartment, and a second composition in a second compartment, where the first and second compartments are joined together, as recited in claim 1. Those formulation taught by Soares et al. employ retinoid compositions useful for anti-wrinkle, and sunscreen dermal applications. See column 3, Table I; column 4, lines 59-64; TABLE III, column 8, and TABLE IV, column 9. Soares also teach a first composition, containing retinoid, and a second composition containing genistein, which are joined together. See TABLE III, column 8, and TABLE IV, column 9.

From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to add phytoestrogens such as genistein, diadzein to the compositions of Granger et al. since phytoestrogens are used to treat skin conditions such as wrinkled, photodamaged skin. It is generally considered a prima facie obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Granger, and Gorbach the instant claims contain compounds retinoids, glycyrrhetic acid, and phytoestrogens used for improvement of skin appearance. *In re kirkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a two compartment system for separately storing retinal or retinyl

ester in a first composition, and retinoid boosters such as glycyrrhetic acid, linoleic acid, phosphatidylcholine and phytoestrogens in the second composition.

One having ordinary skill in the art would have been motivated at the time of invention to employ two compartments to separately store retinol or retinyl ester, and retinoid booster glycyrrhetic acid and phytoestrogens because Liu et al. teach that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation. Moreover, several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together) and are mixed together just prior to use based on the teachings of Liu. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and retinoid boosters, phytoestrogens in the second composition to keep retinol or retinyl ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Further, Soares et al. also employ a dual container system for multi composition use, and teaches the desirability of providing the two compartment product to maximize the effectiveness of the separate compositions, and teaches retinoids in one of the

compositions. Those formulations taught by Soares et al employ retinoic acid in one compositions and phytoestrogen, genistein in another composition which are joined together useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been further motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherently present in the compositions. The skilled artisan would have seen the separate packaging teachings Soares et al. useful for individual application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Thus, the teachings of Liu in particular and Soares et al. have clearly provided the motivation to employ the separate compartments herein.

Regarding the recitation "wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", and the recitation that the components of the second composition act as "boosting the first benefit", as recited in the claims, it is noted that the boosting activity and inhibition of degradation of retinoic acid by a compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137 USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the

Claims 1, 2, 5, 6, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (US 5,723,139, PTO-892), Gorbach (WO 98/56373,

PTO-892), and Meybeck (FR 2 777 179; PTO-892) in view of Liu et al. (5,976,555, PTO-892), and Soares et al. (US 5,914,116, PTO-1449 of record).

Granger et al., and Gorbach are as discussed above.

Granger et al. do not teach the presence of phosphatidylcholine in the composition.

Granger et al. do not teach the storage of first composition comprising retinoid, and second composition comprising retinoid boosters, phytoestrogens, in separate compartments joined together.

Meybeck et al. teach cosmetic and skin care compositions comprising retinoid, retinoid boosters such as 22-29 % of phosphatidyl choline, 0.1 % of glycyrrhetic acid. These compositions can be used for treating skin conditions such as acne, aged skin, dry skin, etc. See page 3, lines 24-27; pages 8-9, Examples 1-2.; page 13, Example 11.

From the teachings of Meybeck et al., it would have been obvious to a person of ordinary skill in the art at the time of invention to add retinoid booster, phosphatidyl choline to the compositions of the Granger et al., since phosphatidyl choline is used to treat skin conditions such as dry skin, aged skin, acne etc. From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to add phytoestrogen such as genistein to the compositions of Granger et al. since phytoestrogens are used to treat skin conditions such as wrinkled, aged, and photodamaged skin. It is generally considered a prima facie obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. The idea of

combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Granger, Gorbach, and Meybeck et al., the instant claims contain compounds such as retinoids, phosphatidyl choline, glycyrrretinic acid and phytoestrogens used for improvement of skin appearance. *In re kirkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ a two compartment system for separately storing retinal or retinyl ester in a first composition, and retinoid boosters such as glycyrrretinic acid, linoleic acid, phosphatidylcholine and phytoestrogens in the second composition.

One having ordinary skill in the art would have been motivated at the time of invention to employ two compartments to separately store retinol or retinyl ester, and retinoid booster glycyrrretinic acid and phytoestrogens because Liu et al. teach that the skin compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation. Moreover, several known stable skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients (the first and second compositions are known to be stored in respectively separate compartments or containers, being joined together) and are mixed together just prior to use based on the teachings of Liu. Therefore, one of ordinary skill in the art would have found it obvious to employ two compartments for separately storing retinol or retinyl ester in a first composition and

retinoid boosters, phytoestrogens in the second composition to keep retinol or retinyl ester from reacting with retinoid boosters and phytoestrogens in order to preserve the stability of retinoids in the compositions to avoid chemical degradation, and keep retinoids from chemical reactions with other ingredients to avoid chemical degradation.

Further, Soares et al. also employ a dual container system for multi composition use, and teaches the desirability of providing the two compartment product to maximize the effectiveness of the separate compositions, and teaches retinoids in one of the compositions. Those formulations taught by Soares et al employ retinoic acid in one compositions, and phytoestrogen, genistein in another composition which are joined together useful for dermal application (see column 4, line 24). Possessing this teaching the skilled artisan would have been further motivated to employ the dual container dermal administration system for the application of dermal medicaments, while enjoying those benefits inherent in sequential application as set forth in Soares et al. claim 1. The skilled artisan would have seen the separate packaging teachings Soares et al. useful for individual application of dermal retinoic acid compositions, and the administration of these compositions dermally and individually as residing in the skilled artisan purview.

Thus, the teachings of Liu in particular and Soares et al. have clearly provided the motivation to employ the separate compartments herein.

Response to Arguments

Applicant's arguments have been considered, but not found persuasive in view of the new ground(s) of rejections presented in this office action, and those found below.

Applicant argues that "There is no teaching whatsoever in the '555 reference that even remotely suggests the combination of specific retinoids with specific boosters and phytoestrogens as claimed in the present invention whereby the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid. The two component system as claimed in this invention, as well as the two preferred boosters as claimed in this invention are not even remotely suggested by the '555 reference which, again, employs a complicated oil-in-water emulsion system to stabilize certain retinoids." These arguments have been considered, but not found persuasive. It is pointed out that applicant is arguing against a single reference, when the rejection was based on combination of references. Liu et al. '555 reference was employed for its teachings that skin care compositions containing retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients. Liu et al. teach that the skin care compositions containing retinol or retinyl esters are unstable as they quickly lose their activity by, for example, either being oxidized or isomerizing to non-efficacious chemical forms and chemical degradation, and thus to keep retinoids from chemical reactions with other ingredients they must be stored separately and are mixed together just prior to use. For example, Avon products sells Bioadvance, and Biodvance 2000 (see also US 6,068,847), each of these products are supplied in separate bottles, the first bottle contains skin lotion, and the second bottle contains retinoids. The two products are mixed prior to use due to the instability of retinoids.

Further, regarding the recitation "wherein the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid", and the recitation that the components of the second composition act as "boosting the first benefit", as recited in the claims, it is noted that the boosting activity and inhibition of degradation of retinoic acid by a compound are properties thereof. It is pointed out that a product and its properties are inseparable. In re Papesch, 315 F.2d 381,137 USPQ 43 (CCPA 1963). Accordingly, the composition rendered obvious by the combined references would, absent evidence to the contrary, meet the limitations pertaining to the retinoid boosting activity of the compound, and inhibition of degradation of retinoic acid by the compound used therein.

Applicant argues that "the '116 reference merely describes a method for a skin treatment regime wherein a first and second composition are stored in separate containers and only connected to each other to remind the consumer to use the compositions in tandem and to facilitate in one sale all necessary elements of a suggested regime. Thus, the '116 reference clearly teaches away from the present invention and cures none of the Vast deficiencies of the primary reference since it discloses two separate containers for separating two different skin actives for two different benefits. Moreover, the reference fails to even remotely teach, suggest or disclose the need to separate phytoestrogens from retinoids. The present invention, again, is directed to two separate compositions with one intended to boost the benefit of the other. Again, according to the present invention, the two compositions are intended to be applied simultaneously or consecutively, but are kept separately for stability reasons." These arguments have been considered, but not found persuasive. It is

pointed out that applicant is arguing against a single reference when the rejection was based on combination of references. From the teachings of Gorbach, it would have been obvious to a person of ordinary skill in the art at the time of invention to employ phytoestrogens such as genistein, diadzein in combination with retinoids, and glycyrrhetic acid for treating wrinkles. It is generally considered a prima facie obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition, which is used for the very same purpose. Soares et al. teaches that skin care compositions are kept separate because single formulations often compromise the performance of the severally combined actives see column 1, lines 15-25, in particular. Further, Soares et al. teaches the employment of a dual container system that allows two compositions to be separated from one another, to maximize the effectiveness of the separate compositions, while also allowing for application of both compositions from a single product, and also provides an example wherein one composition contains retinoid, and a second composition contains genistein. Liu et al. teaches that retinol or retinyl esters are known to be supplied in two bottles or two portions to separate retinoids from other cosmetic ingredients to keep retinoids from chemical reactions with other ingredients. Accordingly, from the teachings of Soares et al., and Liu there is clear motivation to provide a composition comprising retinoid in a first compartment, and a second composition comprising retinoid booster and phytoestrogen in a second compartment, where the first and second compartments are joined together i.e retinoids are kept separate from other actives for stability reasons.

Conclusion

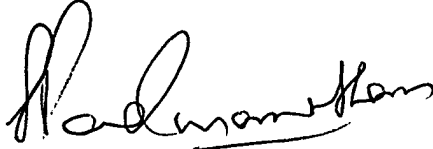
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
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